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Substitute for form 1449A/PTO				<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number 09/668,482 Filing Date September 25, 2000 First named Inventor PETKOVICH Group Art Unit 1652 Examiner Name SLOBODYANSKY, E. Atty Docket Number 57600/00035	TECH 03 FEB REC'D ENTERED +6 RECEIVED JULY 11 2001
Sheet	1	of	1		

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				Group Art Unit	1652
				Examiner Name	SLOBODYANSKY, E.
				Atty Docket Number	57600/00035

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SS	1	ADAMSON P.C. et al., "Time Course of Induction of Metabolism..." Cancer Research, 53: 472-476 (1993).			
	2	BOYLAN J.F. et al., "Targeted Disruption of Retinoic Acid Receptor..." Molecular and Cellular Biology, 15: 2, 843-851 (Feb. 1995).			
	3	DE COSTER R. et al., "Experimental Studies with Liarozole..." J. Steroid Molec. Biol., 43: 1-3, 197-201 (1992).			
	4	FORELLA, P.D. et al., "Microsomal Retinoic Acid Metabolism..." Journal of Biological Chemistry, 269: 14, 10538-10544 (April 1994).			
	5	DENISON, M.S. et al., "Xenobiotic-inducible transcription of cytochrome P450 genes", J. Biol. Chem., 270: 18175-18178 (1995).			
	6	DUELL, E.A. et al., "Human skin levels of retinoic acid and cytochrome P-450-derived 4-hydroxyretinoic acid after topical application of retinoic acid in vivo compared to concentrations required to stimulate retinoic acid receptor-mediated transcription in vitro", J. Clin. Invest., 90: 1269-1274 (1992).			
AV	7	DUELL, E.A. et al., "All-trans, 9-cis and 13-cis retinoic acid each induce a cytochrome P450 4-retinoic acid hydroxylase which causes all-trans but not 9-cis or 13-cis retinoic acid to self-metabolize", SID Abstracts, 102: 641 (1994). Dermatology			
	8	FROLIK, C.A., et al., "Isolation and identification of 4-hydroxy- and 4-oxoretinoic acid. In vitro metabolites of all-trans-retinoic acid in hamster trachea and liver", Biochemistry, 18: 2092-2097 (1979).			
	9	MUINDI, J.R.F. et al., "Clinical pharmacology of all-trans retinoic acid", Leukemia, 8: S16-S21 (1994).			
	10	ROBERTS, A.B. et al., "In vitro metabolism of retinoic acid in hamster intestine and liver", J. Biol. Chem., 254: 6296-6302 (1979).			
	11	ROBERTS, A.B. et al., "Retinoid-dependent induction of the in vivo and in vitro metabolism of retinoic acid in tissues of the vitamin A-deficient hamster", J. Biol. Chem., 254: 6303-6309 (1979).			
	12	TAKATSUKA, J. et al., "Retinoic acid metabolism and inhibition of cell proliferation: an unexpected liaison", Cancer Res., 56: 675-678 (1996).			
	13	VAN WAUWE, J.P., et al., "Ketoconazole inhibits the in vitro and in vivo metabolism of all-trans-retinoic acid", J. Pharm. Exp. Ther. 245: 718-722 (1988).			
	14	VAN WAUWE, J.P. et al., "Effects of cytochrome P-450 inhibitors on the in vivo metabolism of all-trans-retinoic acid in rats", J. Pharm. Exp. Ther. 252: 365-369 (1990).			
SS	15	VAN WAUWE, J.P. et al., "Liarozole, an inhibitor of retinoic acid metabolism, exerts retinoid-mimetic effects in vivo", J. Pharm. Exp. Ther. 261: 773-779 (1992).			

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<i>ES</i>	16	WILLIAMS, J.B., et al., "Inhibition of retinoic acid metabolism by imidazole antimycotics in F9 embryonal carcinoma cells", Biochem. Pharm. 36: 1386-1388 (1987).			
	17	WOUTERS, W., et al., "Effects of liarozole, a new antitumoral compound, on retinoic acid-induced inhibition of cell growth and on retinoic acid metabolism in MCF-7 human breast cancer cells", Cancer Res. 52: 2841-2846 (1992).			
	18	ACHKAR, C.C. et al., "4-Oxoretinol, a new natural ligand and transactivator of the retinoic acid receptors", Proc. Natl. Acad. Sci. USA, 93: 4879-4884 (1996).			
	19	AKIMENKO, M.-A. et al., "Anterior duplication of the Sonic hedgehog expression pattern in the pectoral fin buds of zebrafish treated with retinoic acid", Dev. Biol., 170: 243-247 (1995).			
	20	AKIMENKO, M.-A. et al., "Differential induction of four msx homeobox genes during fin development and regeneration in zebrafish", Development, 121: 347-357 (1995).			
	21	AKIYOSHI-SHIBATA, M. et al., "Further oxidization of hydroxycalcidiol by calcidiol 24-hydroxylase. A study with the mature enzyme expressed in Escherichia coli", Eur. J. Biochem., 224: 335-343 (1994).			
	22	BLUMBERG, B. et al., "Novel retinoic acid receptor ligands in Xenopus embryos", Proc. Natl. Acad. Sci. USA, 93: 4873-4878 (1996).			
	23	BOYLE, A.L. et al., "Rapid physical mapping of cloned DNA on banded mouse chromosomes by fluorescence in situ hybridization", Genomics 12: 106-115 (1992).			
	24	CASTONGUAY, A. et al., "Expression of xenobiotic-metabolizing enzymes in cultured rat tracheal epithelial cells", Environ. Health Perspect. 103: 254-258 (1995).			
	25	CHAMBON, P., "The molecular and genetic dissection of the retinoid signaling pathway", Recent Progress in Hormone Research, 50: 317-332 (1995).			
	26	CHEN, K.-S., et al., "Cloning of the human 1 α ,25-dihydroxyvitamin D-3 24-hydroxylase gene promoter and identification of two vitamin D-responsive elements", Biochim. Biophys. Acta, 1263: 1-9 (1995).			
	27	COSTARIDIS, P. et al., "Endogenous retinoids in the zebrafish embryo and adult", Dev. Dynamics, 205: 41-51 (1996).			
	28	CREECH KRAFT, J. et al., "Temporal distribution, localization and metabolism of all-trans-retinol, didehydroretinol and all-trans-retinal during Xenopus development", Biochem J., 301: 111-119 (1994).			
<i>ES</i>	29	FORELLA, P.D. et al., "Expression of cellular retinoic acid-binding protein (Type II) in Escherichia coli", J. Biol. Chem., 268: 21545-21552 (1993).			

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ES	30	GREEN, S., et al., "A versatile in vivo and in vitro eukaryotic expression vector for protein engineering", Nucl. Acids Res., 16: 369 (1988).			
	31	GUBLER, M.L. et al., "Metabolism of Retinoic Acid and Retinol..." Methods in Enzymology, 189, 525-530 (1990).			
	32	GUENGERICH, F.P., "Reactions and significance of cytochrome P-450 enzymes", J. Biol. Chem., 266: 10019-10022 (1991).			
	33	HAN, I.S. et al., "Highly specific cytochrome P450-like enzymes for all-trans-retinoic acid in T47D human breast cancer cells", J. Clin. Endocr. Metab. 81: 2069-2075 (1996).			
	34	HENG, H.H.Q. et al., "Modes of DAPI banding and simultaneous in situ hybridization", Chromosoma, 102: 325-332 (1993).			
	35	HILLIER, et al., Accession R51129, EST-STS, EST-STS-Two databases (May, 1995).			
	36	JONES, B.B. et al., "New retinoid X receptor subtypes in zebra fish (<i>Danio rerio</i>) differentially modulate transcription and do not bind 9-cis retinoic acid", Mol. Cell. Biol., 15: 5226-5234 (1995).			
	37	LAMMER, E.J. et al., "Retinoic acid embryopathy", N. Engl. J. Med., 313: 837-841 (1985).			
	38	LEO, M.A. et al., "Metabolism of retinol and retinoic acid by human liver cytochrome P450IIC8", Arch. Biochem. Biophys. 269: 305-312 (1989).			
	39	LEO, M.A. et al., "Retinoic acid metabolism by a system reconstituted with cytochrome P-450", Arch. Biochem. Biophys. 234: 305-312 (1984).			
	40	LIANG, P. et al., "Differential display of eukaryotic messenger RNA by means of the polymerase chain reaction", Science, 257: 967-971 (1992).			
	41	LICHTER, P. et al., "High-resolution mapping of human chromosome 11 by in situ hybridization with cosmid clones", Science, 247: 64-69 (1990).			
	42	MADEN, M. et al., "Retinoic acid and development of the central nervous system", BioEssays, 14: 431-438 (1992).			
	43	MAKIN, G. et al., "Target cell metabolism of 1,25-dihydroxyvitamin D3 to calcitriol", Biochem. J., 262: 173-180 (1989).			
	44	MANGELSDORF, D.J. et al., "The RXR heterodimers and orphan receptors", Cell 83: 841-850 (1995).			
ES	45	MARTINI, R. et al., "Participation of P450 3A enzymes in rat hepatic microsomal retinoic acid 4-hydroxylation", Arch. Biochem. Biophys. 303: 57-66 (1993).			

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4

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SG	46	MARTINI, R. et al., "Retinal dehydrogenation and retinoic..." Biochemical Pharmacology, 47, No. 5, 905-909, 1994.	
	47	MARIKAR, Y. et al., "Regulation, properties, and solubilization of a unique cytochrome P-450 that specifically metabolizes all-trans retinoic acid to less active 4-hydroxy retinoic acid in human keratinocyte HACAT cells", Abstract, J. Invest. Dermatol. 106(4): 807 (1996).	
	48	MONIA, B.P. et al., "Antitumor activity of a phosphorothioate antisense oligodeoxynucleotide targeted against C-raf kinase", Nature Med., 2: 668-675 (1996).	
	49	MORRISS-KAY, G., "Retinoic acid and craniofacial development: molecules and morphogenesis", BioEssays, 15: 9-15 (1993).	
	50	MUINDI, J.R.F. et al., "Clinical pharmacology of oral all-trans retinoic acid in patients with acute promyelocytic leukemia", Cancer Res., 52: 2138-2142 (1992).	
	51	MUINDI, J.R.F., et al., "Clinical pharmacology of all-trans retinoic Acid" Liekemis 8:1807-1812 (1994).	
	52	MUINDI, J.F. et al., "Lipid Hydroperoxides Greatly Increase the Rate..." Cancer Research, 53, 1226-1229 (March 1993).	
	53	MURTHA, M.L. et al., "Detection of homeobox genes in development and evolution", Proc. Natl. Acad. Sci. USA, 88: 10711-10715 (1991).	
	54	NAPOLI, J.L. et al., "The biosynthesis of retinoic acid from retinol by rat tissues in vitro", Arch. Biochem. Biophys., 255: 95-101 (1987).	
	55	NELSON, D.R. et al., "The P450 superfamily: update on new sequences, gene mapping, accession numbers, early trivial names of enzymes, and nomenclature", DNA and Cell Biol., 12: 1-51 (1993).	
	56	OGURA, T. et al., "A retinoic acid-triggered cascade of HOXB1 gene activation", Proc. Natl. Acad. Sci. USA 92: 387-391(1995).	
	57	OHYAMA, Y. et al., "Identification of a vitamin D-responsive element in the 5'-flanking region of the rat 25-hydroxyvitamin D3 24-hydroxylase gene", J. Biol. Chem., 269: 10545-10550 (1994).	
SG	58	PIJNAPPEL, W.W.M. et al., "The retinoid ligand 4-oxo-retinoic acid is a highly active modulator of positional specification", Nature, 366: 340-344 (1993).	
	59	RANER, G.M. et al., "Metabolism of all-trans, 9-cis, and 13-cis isomers of retinal by purified isozymes of microsomal cytochrome P450 and mechanism-based inhibition of retinoid oxidation by citral", Mol. Pharmacol. 49: 515-522 (1996).	

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S	60	REDDY, A.P. et al., "Characterization and purification of human retinoic acid receptor- γ 1 overexpressed in the baculovirus-insect cell system", Biochem J., 287: 833-840 (1992).
	61	THALLER, C., et al., "Isolation of 3,4-didehydroretinoic acid, a novel morphogenetic signal in the chick wing bud", Nature, 345: 815-819 (1990).
	62	TOMITA, S., et al., "Characteristic properties of a retinoic acid synthetic cytochrome P-450 purified from liver microsomes of 3-methylcholanthrene-induced rats", Biochim. Biophys. Acta 1290: 273-281 (1996).
	63	WHITE, J.A., et al., "A zebrafish retinoic acid receptor expressed in the regenerating caudal fin", Development, 120: 1861-1872 (1994).
	64	WHITE, J.A., et al., "Identification of the retinoic acid-inducible all-trans-retinoic acid 4-hydroxylase", J. Biol. Chem. 271: 29922-29927 (1996).
/	65	WINDHORST, D.B., "The use of isotretinoin in disorders of keratinization", J. Am. Acad. Dermatol. 6: 708-709 (1982).
S	66	ZIEROLD, C. et al., "Two vitamin D response elements function in the rat 1,25-dihydroxyvitamin D 24-hydroxylase promoter", J. Biol. Chem., 270: 1675-1678 (1995)

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